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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,902	08/03/2001	Amine Abina	065691-0246	9796

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EXAMINER	
PAPPU, SITA S	

ART UNIT	PAPER NUMBER
1632	6

DATE MAILED: 12/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/920,902	Applicant(s) ABINA, AMINE	
	Examiner Sita S Pappu	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-48 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 19-22, 27, 29-30, 43-47, drawn to a method of inhibiting neutralizing antibodies directed against a heterologous protein, by administering the nucleic acid encoding the heterologous protein, classified in class 514 subclass 44.

II. Claims 1-16, 19-22, 27, 29-30, 43-47drawn to drawn to a method of inhibiting neutralizing antibodies directed against a heterologous protein, by administering the heterologous protein, classified in class 514, subclass 2.

III. Claims 17-18, drawn to a method of producing the transgenic mammal expressing a heterologous protein, classified in class 800, subclass 14.

IV. Claims 23-26, 28, drawn to a method of modulating in a mammal, formation of neutralizing antibodies, classified in class 424, subclass 130.1+.

V. Claims 31-39, 43-47, drawn to the use of a method to produce a mammal with a functional inactivation of an endogenous protein and uses of mammal, classified in class 800, subclass 14.

VI. Claim 40, drawn to the use of a mammal to isolate spleen cells to make hybridomas, classified in class 435, subclass 326+.

VII. Claim 41, drawn to the use of biological fluid to prepare serum and/or polyclonal antibodies, classified in class 530, subclass 387.1+.

VIII. Claims 42, 48, drawn to a method to produce vaccine, classified in class 424, subclass 184.1+.

Claims 1-16, 19-22, 27, 29-30 embrace the Inventions of groups I and II. Should one of these groups be elected, the claims 1-16, 19-22, 27, 29-30 will be examined to the extent they encompass the elected subject matter.

Claims 43-47 embrace the Inventions of groups I, II and V. Should one of these groups be elected, the claims 43-47 will be examined to the extent they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Invention I is drawn to the administration of the agent and a nucleic acid encoding a heterologous protein and, thus directed to gene therapy while Invention II is directed to the administration of the agent and a heterologous protein and, thus directed to protein therapy. Thus, Inventions I and II are distinct from each other. The methods require different starting materials, different modes of operation and produce different effects. Further, proteins and nucleic acids are substantially different in terms of structural, chemical, physical and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be synthesized or purified from cells.

Invention III is directed to a transgenic mammal and involves methods that are materially different from those of Inventions I and II. The method of producing a transgenic animal requires materials and steps that are distinct from those of gene and protein therapy methods, which require substantially different modes of administration of the nucleic acid and/or heterologous protein.

Invention IV is directed a method of modulating the formation of neutralizing antibodies by triggering the production of antibodies, in a mammal and involves materially different methods. While Inventions I and II are directed to methods of inhibiting the neutralizing antibodies, Invention IV is directed to a method of triggering the neutralizing antibodies. Invention III encompasses the use of a transgenic mammal while Invention IV does not require the transgenic mammal. Thus, Invention IV is distinct from Inventions I-III.

Invention V involves the use of a method to produce a mammal with a functionally inactivated gene and use it to perform biological, physiological, biochemical and molecular studies, and for drug screening that involve materially different steps and protocols from those of Inventions I-IV. While Inventions I and II are directed to gene and protein therapy, Invention V is directed to the methods of using a mammal with a functionally inactivated gene for in vivo studies. Invention III is directed to a transgenic mammal while Invention V is directed to a mammal that is not transgenic. While Invention V is directed to a mammal with a functionally inactivated gene, Invention IV is directed to a mammal that has no functional inactivation of a gene.

Inventions VI-VIII, iinvolve the use of a mammal to isolate spleen cells to produce hybridomas, to produce serum and/or polyclonal antibodies, and to produce vaccine respectively, and involve materially different steps and protocols, distinct from the other groups. Further, the methods of producing the hybridomas of Invention VI require materials and steps that are distinct from those Invention VII and VIII. The methods of producing the polyclonal antibodies of Invention VII are require different starting materials, and production and screening steps and are thus distinct from those of Inventions VI and VIII. Production of vaccine of Invention VIII requires the use of starting materials and steps that are distinct from those of Inventions VI and VII.

Thus, the groups I-VIII are materially different and distinct from one another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed inventions: the said agent of these inventions is selected among viruses, liposomes, antibodies, parasites, bacteria, fungi, and or fragments thereof, and nucleic acid sequence encoding said heterologous protein.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 2 is generic to the above claimed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (9:00 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Crouch, acting SPE, can be reached on (703) 308-1126. The fax phone numbers for the organization where this application is assigned are (703) 746 7442 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group patent analyst whose telephone number is (703) 305-2758.

Anne-marie Baker

S. Pappu
December 21, 2001

ANNE-MARIE BAKER
PATENT EXAMINER